

REMARKS

Applicants submit this Amendment and Reply ("Amendment") in response to the Office Action mailed November 5, 2003. This response is being filed within three months following the three month shortened statutory period for response. A Petition for an Extension of Time of Three Months and the requisite fee accompany this Reply. A Supplemental Information Disclosure Statement and the requisite fee also accompany this Reply.

Claims 1-5, 7-11, 13-21, 35-44, 46-58 and 60-74 were pending and considered by the Examiner in his Office action. Claims 1-4, 7, 8, 10, 13-15, 17, 19-21, 35-37, 39, 46, 48-52, 54, 55, 58, 61, 62, 65-69 have been amended; claims 11 and 70-73 have been cancelled; and claims 76-95 have been added. Following entry of this Amendment, claims 1-5, 7-10, 13-21, 35-44, 46-58, 60-69 and 74-95 are pending in the application, with claims 1, 35, 36, 39, 46, 50, 69 and 74 being in independent format.

Claim 1 has been amended to specify inducing a *detectable* tissue displacement *at a CNS target tissues site, determining the induced tissue displacement and relating the induced tissue displacement with a physiological property of the CNS target tissue*. This aspect of applicants' claimed invention is referred to in the specification as the first "active" acoustic mode and is described throughout the specification. Application of an acoustic radiation force or ultrasound beam sufficient to induce a detectable displacement in the CNS tissue is described in the specification, for example, at the paragraph spanning pages 31 and 32. Claims 2, 3, 5, 7, 8, 10, 13, 14, 15, 17, 19, 20 and 21 have been amended for purposes of clarification and to conform to the amended claim 1. Claim 4 has been amended to specify that the acoustic data relates to at least one of the amplitude, phase *and frequency* of acoustic scatter. Claim 11 has been cancelled. Claim 75 has been added to specify numerous parameters of acoustic data. These parameters are described in the specification, for example, at page 22. Claim 76 has been added to specify induced tissue displacement parameters that are described in the specification, for example, at page 32.

Claim 35 has been amended to specify a method for assessing a physiological parameter of a CNS target tissue by inducing oscillation of the CNS target tissue; measuring at least one of the frequency *and amplitude* of an emitted acoustic signal, and relating at least one of the frequency *and amplitude* of the emitted acoustic signal to a physiological property of the CNS target tissue. Use of amplitude measurements in this context is described in the specification, for

example, at page 53. Newly added claims 92-94 depend from claim 35 and describe features of applicants' method that are described in the specification, for example, at page 53.

Claim 36 has been amended to specify assessing ICP by administering acoustic interrogation signals to a target CNS tissue site, detecting at least one of an acoustic emission, an induced and an intrinsic target tissue displacement based on acoustic data, determining ABP, and relating the at least one of the acoustic emission, induced and intrinsic target tissue displacement and ABP with ICP. Claim 37 has been amended for purposes of clarity and to conform to the amendments presented in amended claim 36. Newly added claims 77-85 are dependent from claim 36 and specify additional features that have been previously presented in dependent claims. Support for the claim amendment and newly added claims may be found throughout the specification as filed.

Claim 39 has been amended to specify that the system comprises a controller having the capability to process acquired acoustic data, make determinations of at least one of acoustic emission properties, induced and intrinsic tissue displacements, and to relate the determination with at least one physiological condition of a CNS target tissue. Support for this claim amendment may be found throughout the specification as filed.

Claim 46 has been amended to recite a subject, to provide a proper antecedent basis and to correct a grammatical error. Claims 48 and 49 are amended to clarify the claimed subject matter and change the dependency. Newly added claims 86-91 depend from claim 46 and specify additional features of the claimed method. Support for the newly added claims may be found in the specification, for example, at pages 18-19.

Claim 50 has been amended to specify acquiring acoustic data relating to intrinsic tissue displacements at the CNS target tissue site and relating *the intrinsic tissue displacements* with a physiological property of the CNS target tissue. This aspect of applicants' claimed invention is described in the specification as the "passive" acoustic mode, for example at page 28. Newly added claim 95 specifies comparing the intrinsic tissue displacements with an empirically determined standard, which is described in the specification, for example, at page 20, line 10.

Claims 54, 55, 58, and 61 have been amended to delete reference to cancelled claims, and claims 70-73 have been cancelled.

Claims 62, 65, 66, 67 and 68 have been amended for purposes of clarification and to conform to amendments made to claims from which they depend.

Claim 69 has been amended to incorporate the subject matter of claim 70, which has been cancelled, and to specify a method for assessing a physiological property of *a CNS target tissue*.

It is urged that no new matter has been introduced to the application.

Claim 46 was objected to and correction required. Claim 46 has been amended to make the appropriate correction.

Patentability under 35 U.S.C. § 102(e).

Claims 1-5, 7-11, 13-21, 35-44, 46-58 and 60-74 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent 6,328,694B1 ("Michaeli"). Applicants respectfully traverse the stated grounds of rejection and submit that Michaeli does not anticipate, nor does it render obvious any of the pending claims.

Michaeli is cited as a 102(e) reference. The patent issued December 11, 2001 from an application filed May 26, 2000. The subject application was filed November 28, 2001, claiming priority to a U.S. provisional patent application filed November 28, 2000. Applicants' priority claim under 35 U.S.C. 119(e) has been acknowledged. Applicants do not concede that Michaeli is an effective prior art reference against all or any of the pending claims and preserve all rights to establish an earlier date of invention at a later time. For purposes of this response, however, applicants would prefer to argue the merits of the rejection and demonstrate that Applicants' pending claims are allowable in view of Michaeli.

Michaeli describes apparatus and methods for tissue resonance analysis involving generating an ultrasound pulse that propagates through the skull and brain of the patient and is reflected off the skull and soft tissue lying in a path perpendicular to the ultrasound probe. The reflected signals are processed, in a known manner, to generate an echo encephalogram (Echo EG), which is plotted as a function of amplitude vs. distance. A portion of the Echo EG signal is selected and integrated over the selected portion to generate an echo pulsograph (EPG) signal. Using an ECG signal as a reference, the EPG signal is used to provide information regarding the physiological state of tissue. In one specific embodiment, the EPG signal is used to provide a quantitative measure of ICP using the relationship described in Michaeli at Col. 8, line 7.

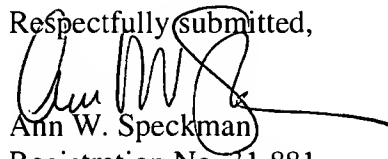
Applicants' pending claims 1-5, 7-10, 13-21, 35-44, 50-58, 60-68, 74-85 and 92-95 relate to methods and systems for detecting a physiological property of a CNS target tissue comprising, among other things, noninvasively inducing a detectable tissue displacement at a CNS target tissue site, inducing an oscillation at a CNS target tissue site, or detecting an intrinsic tissue displacement at a CNS target tissue site and relating the induced tissue displacement, the

acoustic emission produced by the induced oscillation, or the detected intrinsic tissue displacement, to a physiological property of CNS tissue. It is not perceived that Micheali discloses or suggests methods or systems that induce a detectable tissue displacement or oscillation in CNS target tissue using acoustic techniques. It is also not perceived that Michaeli discloses or suggests methods or systems that relate an induced tissue displacement, the acoustic emission produced by the induced oscillation, or a detected intrinsic tissue displacement, to a physiological property of CNS tissue, such as ICP. It is urged that claims 1-5, 7-10, 13-21, 35-44, 50-58, 60-68, 74-85 and 92-95 are allowable over the prior art of record.

Applicants' pending claims 46-49 and 86-91 relate to a method for localizing a physiological condition or biological response, such as pain, by administering ultrasound pulses to a plurality of targeted tissue sites using a focused acoustic probing technique and, for example, observing the subjective sensation of pain induced. This methodology may be used, for example, to pinpoint specific origins of pain within a generalized area of undifferentiated pain. Applicants do not perceive that the use of a focused acoustic probing technique to localize such a physiological condition, or related biological response, is disclosed or suggested by Michaeli.

It is urged that applicants' pending claims are in condition for allowance. Early reconsideration and allowance of the pending claims is respectfully requested. Should the Examiner continue to have any concerns about the pending claims, he is invited to telephone the applicants' representative at the number listed below.

Respectfully submitted,



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Date: May 5, 2004

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